

## REMARKS

Claims 1-3, 5, 7-8, 10-13, 16, 18-23 and 29 are pending in this application. By this Amendment, claims 6 and 9 are cancelled. Also by this amendment, claims 1-3, 10-11 and 21 are amended. Support for the amendments to claim 1, 2 and 21 may be found, for example, on page 7, line 1 to page 8, line 3 of the original specification. Further support for the amendments to claim 1 and 21 may be found, for example, in columns 1 and 2 of Tables 1 and 2, and column 1 of Table 3. Support for the amendment to claim 3 can be found, for example, on page 3, lines 34-38 of the original specification. Support for the amendment to claims 10-11 can be found, for example, on page 7, line 37 to page 8, line 3. No new matter is added. In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

### **I. Rejection under 35 U.S.C. §102(b)**

The previous Office Action rejects claims 1-3, 5-8, 12, 16, 18-20, 23 and 29 as being anticipated by U.S. Patent No. 5,508,034 to Bernstein ("Bernstein"). However, Bernstein does not disclose every limitation of independent claim 1 as amended, thereby rendering the rejections moot. Thus, the rejection is respectfully traversed.

Amended claim 1 specifically requires a cosmetic composition, a corporal hygiene composition, or a dermo-therapeutic composition that exists in a two phase form and comprises at least 98% by weight of a plurality of biodermal constituents. However, Bernstein does not describe a cosmetic composition, a corporal hygiene composition, or a dermo-therapeutic composition that exists in a two phase form and comprises at least 98% by weight of a plurality of biodermal constituents.

At most, Bernstein teaches a lipid concentrate blended from a combination of the three naturally-occurring lipid groups found in the stratum corneum. The concentrate may be applied topically as prepared. See abstract. However, Bernstein is silent as to the composition being in

diphasic form. In fact, the Office Action, on page 2, paragraph 5, acknowledges that Bernstein "does not specifically teach using a two phase oil-in-water or water-in-oil form." Moreover, since the active ingredients in Bernstein's disclosure are lipid components, it is highly likely that they all require a lipophilic carrier solvent. Consequently, Bernstein's composition would probably be a monophasic composition. Moreover, Bernstein, at column 2, lines 18-21, describes that the "lipid concentrate formulation may be added to cream, ointment, gel or lotion vehicles." Bernstein's Examples 1 and 2 further describe such vehicles. However, Example 1 describes using a "lotion base," which is a monophasic composition, and not a diphasic composition. Additionally, although Example 2 describes blending a mixture formulation into a cream, the cream does not comprise at least 98% by weight a plurality of biodermal constituents. In fact, none of the suitable constituents listed in Example 2, except for liquid concentrate (which only makes up 5% by weight of the cream), are biodermic components. Applicant defines, on page 4, line 31 to page 5, line 2 of the specification, biodermic components as "any component or product *forming part of the composition of the skin, in particular the epidermis*, it being understood that this constituent is considered in isolated form, in a form identical to its natural form, or modified relative to its natural form, but remaining cytocompatible with the skin" (emphasis added). However, the constituents listed in Bernstein's Example 2 are not biodermic components, but are instead, chemical components that do not form the composition of the skin.

On the other hand, as Applicant describes on page 2, lines 21-25, in forming a composition that is 98% by weight composed of biodermal constituents, "it is no longer possible in particular to distinguish between active principle(s) and excipient or vehicle." Thus, "in practice, a product according to the present invention behaves both as one or more active principles and as a excipient." See page 2, lines 25-27. Accordingly, the advantage of the present invention is that it obviates the need for a separate excipient or vehicle.

Because the limitation of a diphasic composition comprising at least 98% by weight a plurality of biodermal constituents as claimed by Applicant is absent from Bernstein's disclosure, Bernstein does not anticipate Applicant's claim 1 and the claims dependent therefrom. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

## **II. Rejection Under 35 U.S.C. §103**

The previous Office Action rejects claims 1, 9-11 and 13 as being unpatentable over Bernstein, and claims 1, 9-11, 16, 21, and 22 as being unpatentable over Bernstein in view of U.S. Patent No. 5,886,041 to Yu ("Yu"). The rejections are respectfully traversed.

As discussed above, claim 1 specifically requires a diphasic composition comprising at least 98% by weight a plurality of biodermal constituents. However, none of Bernstein or Yu, alone or in combination, teach or suggest at least this feature of the claimed invention.

As discussed above, Bernstein does not teach, nor does Bernstein suggest, a diphasic composition comprising at least 98% by weight a plurality of biodermal constituents.

At best, Yu teaches a "preventive as well as therapeutic treatment to alleviate cosmetic conditions and symptoms of dermatological disorders with amphoteric compositions containing alpha hydroxyacids, alpha ketoacids, related compounds or polymeric forms of hydroxyacids." See abstract. Yu, at column 3, lines 30-45, describes some examples of amphoteric substances. Although some of the listed amphoteric substances, such as deacetylated hyaluronic acid, are biodermal constituents, the rest of the compositions listed are made of alphahydroxyacid or alpha ketoacid, which, due to the low pH formulation, have a tendency to irritate human skin upon application. See Yu, column 2, lines 6-8. Accordingly, most of the other amphoteric substances listed are not biodermal constituents.

Yu, at column 12, lines 40-62, describes that the composition may be formulated into "cream, or ointment form" (i.e. diphasic forms). The concentration of the amphoteric or

pseudoamphoteric compounds "may range from 0.01 to 10 M, the preferred concentration ranges from 0.1 to 3 M," and the concentration of hydroxyacids or the related compounds "may range from 0.02 to 12 M, the preferred concentration ranges from 0.2 to 5 M." However, from this description alone, it is difficult to quantify in percent weight of each composition constituent, since the molecular weights of each constituent is not indicated. Moreover, Yu is silent as to the proportion of the mixture containing the aggregate of the amphoteric composition and the hydroxyacid, over the total composition having the form of a cream or an ointment.

Finally, Yu describes formulating the composition into gel form, wherein the amphoteric compounds and hydroxyacid are dissolved in "a vehicle or vehicle system such as water, or ethanol and propylene glycol with or without a gelling agent." See column 12, line 50 to column 13, line 6. The gelling agent is not a bidomeric compound, and instead is, for example, hydroxyethyl cellulose, methyl cellulose, hydroxypropyl cellulose or carbomer. Again, Yu is silent as to the proportion of the mixture containing the aggregate of the amphoteric composition and the hydroxyacid, over the total composition having the form of a gel. Consequently, Yu does not teach or suggest that both phases of the biphasic composition could be constituted of bidermic components representing at least 98% weight of the composition. Morevoer, the teachings of Bernstein, combined with the teachings of Yu, would not have led to the composition of claim 1, since neither Bernstein nor Yu suggest or teach the use of bidermic constituents as a vehicle or excipient for distributed or dispersing the active principle compound.

For the above reasons, it would not have been obvious for one of ordinary skill in the art, in view of the teachings of the cited references, to substitute a diphasic composition comprising at least 98% by weight a plurality of biodermal constituents for any of the lipid concentrate blended from a combination of the three naturally-occurring lipid groups found in

the stratum corneum disclosed by Bernstein or the amphoteric compositions containing alpha hydroxyacids, alpha ketoacids, related compounds or polymeric forms of hydroxyacids as disclosed by Yu. The references neither disclose such a diphasic composition comprising at least 98% by weight a plurality of biodermal constituents, nor any benefits that would be provided by using such a diphasic composition comprising at least 98% by weight a plurality of biodermal constituents.

For at least this reason, any combination of the cited references would not have rendered obvious the claimed invention. Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

### **III. Conclusion**

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of this application are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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Attachment:

Request for Continued Examination

Date: November 7, 2007

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